

Heelbo, Inc.

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K962964

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Heelbo, Inc.
Johnny Grait Belt Security Belt

510(k) Summary

1. 1. Submitter's name, Address and Contact Person

Submitter

Heelbo, Inc.
1134 N. Homan
Chicago, IL

Contact Person

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Date Summary Prepared - October 22, 1996

2. Name of Device:

Heelbo Johnny Grait Belt Security Belt

3. Name of Predicate Device(s)

Heelbo Johnny Grait Belt Security Belt

4. Description of Device

The Heelbo Johnny Grait Belt Security Belt is a security belt made of cotton with a polypropylene, quick release snap buckle closure and two D-Ring Velcro loop fasteners. The belt is 2 inches wide and 60 inches long to accommodate a wide range of patients. The Velcro fasteners quickly attach and detach to chairs, chair commodes, wheelchairs, beds and gurneys.

The Johnny Grait Belt Security Belt is intended to be used as a safety belt to secure a patient who is seated in a wheelchair or geri-chair. It is also used to secure a patient sitting on a chair commode or lying on a bed or gurney.

5. Statement of Intended Use

The Johnny Grait Belt Security Belt is intended to be used as a safety belt to secure a patient who is seated in a wheelchair or geri-chair. It is also used to secure a patient sitting on a chair commode or lying on a bed or gurney.

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Heelbo, Inc. Johnny Grait Belt Security Belt

6. Statement of Technological Characteristics of the Device

The Heelbo Johnny Grait Belt Security Belt is a security belt made of cotton with a polypropylene, quick release snap buckle closure and two D-Ring Velcro loop fasteners. The belt is 2 inches wide and 60 inches long to accommodate a wide range of patients. The Velcro fasteners quickly attach and detach to chairs, chair commodes, wheelchairs, beds and gurneys.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints dated December 1995.

7. Biocompatibility Assessment

The subject devices are identical in components materials to the predicate devices. The suppliers of the materials used in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Johnny Grait Belt Security Belt is safe and effective for it's intended use and is substantially equivalent to the predicate device.